IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Civil Action No. 8:18-cv-883-PWG

NOTICE

Defendants respectfully update the Court on the status of the FDA's March 2019 draft guidance, which proposed modifications to the agency's premarket review compliance policy for certain deemed products. *See* ECF Nos. 59, 155. On January 2, 2020, the FDA posted the final version of that draft guidance. FDA, *Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* (January 2020), https://www.fda.gov/media/133880/download (Ex. A).

Under the final guidance, beginning February 6, 2020, the FDA intends to prioritize enforcement of premarket review requirements for flavored, cartridge-based e-cigarettes (except for menthol and tobacco flavors); all other e-cigarettes for which the manufacturer has failed to take or is not taking adequate measure to prevent minors' access; and any e-cigarette product that is targeted to minors or whose marketing is likely to promote use of e-cigarettes by minors. Guidance at 10; 85 Fed. Reg. 720 (Jan. 7, 2020) (notice of availability). The FDA also intends to prioritize enforcement of any e-cigarette product that is offered for sale after May 12, 2020, and

for which the manufacturer has not submitted a premarket application (or after a negative action by the FDA on a timely submitted application). Guidance at 10–11.

For other deemed products, the FDA intends to prioritize enforcement of premarket review requirements beginning May 12, 2020. ECF No. 127; Guidance at 30. After that date, FDA intends to prioritize enforcement on a case-by-case basis, considering the likelihood of youth use or initiation to make the most efficient use of its resources. Guidance at 31.

A copy of the guidance is attached.

Dated: January 10, 2020

Respectfully submitted,

Of counsel:

ROBERT P. CHARROW
General Counsel
Food and Drug Division
Office of General Counsel
U.S. Dep't of Health and Human Services

STACY CLINE AMIN
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

WENDY S. VICENTE
Senior Counsel

PETER G. DICKOS
Associate Chief Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

JOSEPH H. HUNT
Assistant Attorney General

JAMES M. BURNHAM
Deputy Assistant Attorney General

/s/ *Eric Beckenhauer*
ERIC B. BECKENHAUER
Assistant Director
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, DC 20005
(202) 514-3338
(202) 616-8470 (fax)
eric.beckenhauer@usdoj.gov

Counsel for Defendants